In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 09-427V

Filed: August 29, 2013

* *	**TO BE PUBLISHED**
ANITA ROBERTS and GARY ROBERTS, * Co-petitioners, as Next Friends, Parents * acting on behalf of AMBER D. ROBERTS * their minor child, * * Petitioners, * * * v. * * SECRETARY OF HEALTH * AND HUMAN SERVICES, * * Respondent. *	Special Master Zane Entitlement; tetanus-diptheria-accellular pertussis vaccination ("Tdap"); transverse myelitis ("TM"); oligoclonal banding; infarction; fibrocartilaginous embolism ("FCE")
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Thomas K. Herren, Herren & Adams, Lexington, KY, for Petitioner
Ann D. Martin, United States Dep't of Justice, Washington, DC, for Respondent

PUBLISHED RULING[1]

Petitioners, Anita Roberts and Gary Roberts ("Petitioners"), on behalf of their daughter, Amber Roberts ("A.R."), filed a petition alleging that the tetanus-diptheria-acellular pertussis vaccine ("Tdap") caused A.R. to suffer transverse myelitis. Petition at ¶ 1. Petitioners seek

[1] Because this decision contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, § 205, 44 U.S.C. § 3501 (2006). The decisions of the special master will be made available to the public with the exception of those portions that contain trade secret or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. As provided by Vaccine Rule 18(b), each party has 14 days to file a motion requesting the redaction from this decision of any such alleged material. In the absence of a timely request, which includes a proposed redacted decision, the entire document will be made publicly available. If the special master, upon review of a timely filed motion to redact, agrees that the identified material fits within the categories listed above, the special master shall redact such material from the decision made available to the public. 42 U.S.C. § 300aa-12(d)(4); Vaccine Rule 18(b).

compensation pursuant to the National Childhood Vaccine Injury Act ("Vaccine Act"), as amended, 42 U.S.C. § 300aa-1, *et seq.*[2]

As explained below, upon consideration of the record as a whole, the special master concludes that Petitioners have satisfied their burden of showing by preponderant evidence that the vaccine was a substantial factor in causing A.R.'s autoimmune problem, transverse myelitis ("TM"). As explained below, there is ample evidence to satisfy *Althen's* Prong 1. Petitioners rely on the well-recognized theory of molecular mimicry as the plausible medical theory that explains how the vaccine could have caused A.R.'s injuries. And, there is no dispute regarding *Althen's* Prong 3. The parties' experts agree that the time between vaccination and onset, approximately four weeks, is a medically appropriate temporal relationship.

The parties' primary disagreement relates to *Althen* Prong 2 and whether Petitioners made a sufficient showing that there was a logical sequence of cause and effect between the vaccine and A.R.'s injuries. With regard to this issue, both parties have presented detailed evidence regarding the proper diagnosis of A.R.'s injury, the permanent paralysis of her lower extremities, and whether it was due to an inflammation caused by an autoimmune response, TM, or was the result of an infarction, embolism or FCE. As set forth below, the record, in particular, the clinical evidence and the results of the objective diagnostic tests with supporting medical literature in the record, sufficiently supports Petitioners' claim as to *Althen's* Prong 2. As such, Petitioners have satisfied all three *Althen* Prongs and have satisfied their burden.

BACKGROUND

A. Factual Background

A.R. was born on July 2, 1995. P's Ex. 1. During the first 11 years of her life A.R. was generally healthy. Tr. at 92-93, 108. On July 06, 2006, A.R. visited her pediatrician for a sixth grade check-up. P's Ex. 13 at 26. Although she complained of back pain at that time, the records noted she was generally healthy. P's Ex. 13 at 26. She received a Tdap vaccine.[3] P's Ex. 13 at 51. After receiving the vaccine, A.R. noticed a knot under the skin where she receied the shot and her skin was slightly swollen. Tr. at 108. About a week after receiving the vaccine, A.R. felt her feet tingled a bit while she was riding in her father's truck.[4] Tr. at 109. The tingling was not like the sensation of her legs falling asleep, which she had experienced before. Tr. at 110.

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[2] The National Vaccine Injury Compensation Program ("Vaccine Program") is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. § 300aa-10 through § 300aa-34 (2006).

[3] The record refers to this vaccine as adult dT or Adacel, which is the brand name. Petitioner's Ex. 13 at 26.

[4] Petitioner reported sitting in the back of her father's truck with her legs crossed for 30 to 45 minutes prior to feeling the tingling in her legs. Tr. at 111. Petitioner also reported never experiencing this type of tingling before. *Id.* at 110.

On August 4, 2006, A.R. went to the county fair with her mother, brother, and some of her brother's friends. Tr. at 111-12. While at the fair, A.R. rode some rides. Tr. at 112. A.R. denied having any back or hip pain, Tr. at 112. Her mother said A.R. did not tell her about any pains.[5] Tr. at 95, 112. The next morning A.R.'s mother recalled A.R. complaining of a slight back ache. Tr. at 96.

At some point on August 5, 2006, A.R. went to the bathroom. Tr. at 113. On the way to the bathroom, her feet felt a little heavy although she was still able to walk to the bathroom. Tr. at 114-15. In addition, she had some slight incontinence. Tr. at 113. A.R. sat down on the toilet and her legs got heavy and she could not get back up. Tr. at 113. She fell to the bathroom floor. Tr. at 118. She still had some feeling in her legs but then it started to go away and eventually she felt nothing. *Id.* Her mother and brother helped her up, and they went to the hospital. Tr. at 113-14.

At the hospital, the initial impression was an acute onset of being unable to feel or move her legs. P's Ex. 5 at 1. The notes from A.R's neurologic exam recorded A.R. as having "abnormal proprioception of the right and left lower extremities." P's Ex. 5 at 4. The symptoms were consistent with a central lesion leading to a sensory defect affecting both sides of the body. *Id*. An x-ray of the thoracic spine was taken, which showed no evidence of an acute fracture. *Id.* The primary diagnosis was acute paraplegia. *Id.*

A.R. was transferred by ambulance to the Cincinnati Children's Hospital. P's Ex. 5 at 5. The impression recorded at the time A.R. presented at the emergency department of Cincinnati Children's Hospital was acute onset lower extremity paralysis, afebrile, and without any previous illness. P's Ex. 6A at 1. Magnetic Resonance Imaging ("MRI") of A.R.'s cervical spine and a lumbar puncture were performed. P's Ex. 6A at 5. Cerebral spinal fluid ("CSF") results indicated a protein of 60 and red blood cell count of 8. P's Ex. 11 at 439. It was noted that although the CSF study was considered normal, it was to be repeated because it was still very early after presentation. P's Ex. 11 at 160, 162.

The initial MRI report noted "mild central cord high T2 signal from T10 to the conus." P's Ex. 11 at 142. The impression was that this might represent myelitis, viral infection, or less likely cord ischemia or Guillain-Barre. P's Ex. 6E at 1. Additionally, disc desiccation was observed at L2/L3, L3/L4, L4/L5, and L5/S1 and there was no evidence of cord compression. *Id.* A subsequent addendum note in the report observed an abnormal T2 signal within the cord appeared to extend to the T7 level, although axial T2-weighted images demonstrated motion artifact. P's Ex. 6E at 1. A.R. was admitted to the hospital in stable condition with an ER diagnosis of paraplegia. P's Ex. 6A at 1.

[5] The hospital admission records reflect in the medical history that A.R. complained of bilateral hip pain the night of the fair. P's Ex. 11 at 140; P's Ex. 5 at 1. A.R. disputed this, testifying that the source of this statement was her father who had not been at home with her to have any knowledge of that. Tr. at 114.

On August 6, 2006, the attending physician noted the MRI findings with the T2 signal on at least the T10-T12 segments. P's Ex. 11 a 146. He also noted bilateral flaccid paralysis of the lower extremities. *Id.* His impression was that A.R. had transverse myelitis. *Id.*

On August 10, 2006, repeat CSF studies were performed. P's Ex. 11 at 439-445. The repeat studies showed a white blood cell count of six [reference range: 0-4] and CSF protein at 58 mg/dL [reference range: 12-60 mg/dL]. P's Ex. 11 at 439. Testing of the CSF obtained during the lumbar puncture on August 10, 2006, revealed oligoclonal bands, with the bands also present in A.R.'s serum sample, which had not been present previously. P's Ex. 11 at 439-40. Additionally, the IgG levels had increased from the levels of August 6, 2006. *Id.*

A.R.'s condition did not improve, and she subsequently began intravenous gamma globulin treatment on August 11, 2006, followed by a prednisone taper treatment started on August 12, 2006. P's Ex. 11 at 165-166. A.R.'s condition, however, still did not change. P's Ex. 11 at 165-166, 241.

On August 14, 2006, it was noted that A.R. had "slightly improved sensation" and she was transferred to the inpatient rehabilitation floor with a formal diagnosis of transverse myelitis. P's Ex. 11 at 174; P's Ex. 6C at 1. Over the next month, A.R. received occupational, recreational, and physical therapy. P's Ex. 11 at 243-388. A.R.'s condition, however, did not improve further, and she was discharged on September 15, 2006. P's Ex. 11 at 387.

After the discharge, A.R. was seen by pediatric neurologist, Lois Krousgrill, for a follow up on September 27, 2006. P's Ex. 11 at 390, 491-92. Dr. Krousgrill noted that A.R. had no recovery from motor or sensory function. P's Ex. 11 at 492. Dr. Krousgrill's impression was idiopathic TM. P's Ex. 11 at 489.

A second MRI was performed on November 1, 2006 which showed a subtle hyperintense T2 signal "centrally within the cord at the T6-T7 level." P's Ex. 11 at 1670. The report continued: "Hyperintense T2 signal to a greater degree is noted with the cord from the T8-T9 level to the L1 level." P's Ex. 11 at 1670. The radiologist noted that the signal at the T8-T9 level "likely represents myelomalacia." *Id.* "Significant atrophy" from T8-T9 to the tip of the conus was also observed. *Id.* In addition, the image was remarkable for mild disc desiccation from L2-3 to L5-S1 level, as well as subtle disc bulges at L2-L3, L3-L4, and L4-L5. *Id.*

A.R. was readmitted to Cincinnati Children's hospital for initial plasmapheresis treatments on October 30, 2006 and November, 2, 2006. *Id.* at 519-536. She received further plasmapheresis treatments three times per week over the next two weeks. *Id.* Unfortunately, Amber did not improve upon the treatment and no marked recovery was observed.[6] *Id.*

Despite treatment and therapy, A.R. continued to have a neurogenic bladder/bowel, period decubitis ulcers, multiple UTIs, incontinence, vaginal candidiasis, joint contractures, and constipation since the onset of the acute paralysis symptom. Petition at 2. At the time of hearing, A.R. was in 11th grade, was still in a wheelchair and could not stand or walk. Tr. at 116.

[6] There were ten treatments originally scheduled, but the ninth and tenth were abandoned when A.R. had no recovery after the first eight treatments. Tr. at 99 -100.

B. Procedural History

On July 1, 2009, Petitioners, Gary Roberts and Anita Roberts filed a petition for compensation under the National Vaccine Injury Act if 1986 ("the Vaccine Act"), 42 U.S.C. §300a-10, et seq., as amended, on behalf of her daughter, A.R. Petitioners alleged that A.R. suffered from TM as a result of her receipt of a Tdap vaccine on July 06, 2006. Petition ¶1.

Subsequently, the parties filed expert reports. P's Ex. 14 and R's Ex. A. On October 14, 2010, pursuant to order of the previously assigned Special Master, supplemental expert reports were filed. P's Exs. 18 and 19; R's Exs. C, L and N.[7]

On March 26 and 27, 2012, an entitlement hearing was held in Cincinnati, OH. One of the petitioners, Anita Roberts, and A.R. testified. Tr. at 91 and 107. Three expert witnesses testified on behalf of Petitioners. First, Dr. Lois Krousgrill, a neurologist, who had examined A.R. at and near the time of the onset of A.R.'s injuries, testified. Tr. at 4. She opined that A.R. had TM, not an embolism or infarction or fibrocartilaginous embolism ("FCE")[8] based on her clinical picture and the results of diagnostic tests. Tr. at 89-90. She further testified that she believed there was a relationship between the vaccine and A.R.'s TM. Tr. at 15.

Second, Dr. Sidney Houff, a neurologist, testified. Tr. at 122. Dr. Houff opined that A.R. had suffered from an autoimmune reaction to the vaccine she received which caused her to have transverse myelitis.[9] Tr. at 125.

Third and finally, Dr. Mary Edwards-Brown, a neuroradiologist, testified that this was an unusual case of TM. Tr. at 321. She further concluded that the TM was due to the vaccine. Tr. at 321.

Two experts testified on behalf of Respondent. First, Dr. John Sladky, a neurologist, testified. Tr. at 247. He opined that he believed that A.R.'s clinical features were more indicative of a spinal cord infarction, an embolism or FCE than TM, an inflammatory condition. Tr. at 250. He further opined that even if A.R. had TM, he did not think there was enough evidence to conclude the vaccine caused it. Tr. at 287.

Second, Dr. Louis Vezina, a neuroradiologist, testified. Tr. at 408. Dr. Vezina opined that based on the imaging studies, the findings were consistent with those of a lower spinal cord

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[7] This matter was transferred to this special master in March 2011.

[8] Infarction, embolism and FCE are described in various places in the record and the terms are used interchangeably. In essence, they refer to an event that abruptly stops the blood flow to the spinal cord, *i.e., a* stroke in the spinal cord. R's Ex. C.; *see also* Tr. at 38 (infarction is a blood clot in the spine); Tr. at 36-37 (an embolism was described as a blockage that caused a cut off of blood flow down the spine).

[9] Transverse myelitis (TM) is an acute "inflammatory" disorder of the spinal cord resulting in bilateral motor, sensory, and sphincter deficits below the level of the lesion. R's Ex. E.

infarct although he acknowledged that they could evidence TM. Tr. at 412-414. He deferred to a neurologist to decipher A.R.'s clinical picture. Tr. at 454-455.

APPLICABLE LEGAL STANDARDS

The Vaccine Act provides two means of recovery: Table claims and off-Table claims.[10] In an off-Table, or causation-in-fact case, such as this one, a petitioner must prove actual causation by a preponderance of the evidence. *Moberly v. Sec'y of Health & Human Servs.,* 592 F.3d 1315, 1321 (Fed. Cir. 2010). To prove actual causation, a petitioner must "show that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.' " *Moberly,* 592 F.3d at 1321–22 (quoting *Shyface v. Sec'y of Health & Human Servs.,* 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)). Causation is determined on a case-by-case basis. *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994).

A petitioner satisfies this burden if he or she provides: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). A petitioner must satisfy the three *Althen* prongs by preponderant evidence. *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). This preponderant-evidence standard "simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence." *Moberly,* 592 F.3d at 1322 n.2; *Althen*, 418 F.3d at 1279 (citing *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572–73 (Fed. Cir. 1993)) (noting the standard requires that a petitioner demonstrate the existence of the element is "more probable than not."). Evidence used to satisfy one of the *Althen* prongs can overlap and be used to satisfy another prong. *Capizzano,* 440 F.3d at 1326.

There are no "hard and fast *per se* scientific or medical rules" for finding causation under the Vaccine Act. *Knudsen,* 35 F.3d at 548. The Vaccine Act does provide that a claimant may satisfy the preponderant evidence standard by producing "medical records or a medical opinion." 42 U.S.C. § 300aa-13(a)(1). A petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case. *Moberly,* 592 F.3d at 1322. However, the explanation need only be "legally probable, not medically or scientifically certain." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345-46 (Fed. Cir. 2010); *Moberly,* 592 F.3d at 1322 (quoting *Knudsen,* 35 F.3d at 548-49). Along these lines, a special master may not require "epidemiologic studies. . .or general acceptance in the scientific or medical communities. . . ." *Andreu,* 569 F.3d at 1378.

At the same time, special masters are "entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly,* 592 F.3d at 1324; *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010). In determining reliability, a

[10] In a Table case, unlike the present case, a claimant who shows that he or she received a vaccination listed in the Vaccine Injury Table, 42 U.S.C. § 300aa–14, and suffered an injury listed in the Table within a prescribed period is afforded a presumption of causation. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1374 (Fed. Cir. 2009).

special master may appropriately rely on the standards set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593-94 (1993); *see Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) (finding that special masters' use of the *Daubert* factors reasonable); *Cedillo*, 617 F.3d at 1338-39 (finding no legal error in the standards applied by the special master in utilizing *Daubert)*. When a party relies upon expert testimony, that testimony must have a reliable scientific basis. *Cedillo*, 617 F.3d at 1339. Although a party need not produce medical literature to establish causation, where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury. *Andreu*, 569 F.3d at 1379; *Althen*, 418 F.3d at 1281; *see also Daubert*, 509 U.S. at 593-94.

Causation can be supported by a treating physician's opinion that a vaccination was causally linked to the vaccinee's injury if the special master finds the opinion to be both reliable and persuasive. *Moberly*, 592 F.3d at 1324–25. At the same time, in cases in which a petitioner relies upon expert testimony to prove causation, the expert testimony must rest upon an objective and reliable scientific basis and must prove causation to a degree of legal certainty, but not to a medical or scientific certainty. See *Moberly*, 592 F.3d at 1322 ("A petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'") (quoting *Knudsen*, 35 F.3d at 548–49); *see also Cedillo*, 617 F.3d at 1339; *Terran*, 195 F.3d at 1316. Although a petitioner may rely solely on expert testimony, "[a]n expert opinion is no better than the soundness of the reasons supporting it." *Perreira v. Sec'y of Health & Human Servs.*, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994). Therefore, a special master does not need to credit "expert opinion testimony that is connected to the existing data or methodology 'only by the *ipse dixit* of the expert,' or where 'there is simply too great an analytical gap between the data and the opinion proffered.'" *Jarvis v. Sec'y of Health & Human Servs.*, 99 Fed. Cl. at 61 (quoting *Cedillo*, 617 F.3d at 1339).

With regard to alternative causes, the respondent bears the burden of proving by preponderant evidence that an alternative cause, or factor unrelated, was the sole cause of the injury. 42 U.S.C. § 300aa-13; *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1354 (Fed. Cir. 2008); *Knudsen*, 35 F.3d at 549. But, neither 42 U.S.C. § 300aa-13 nor the decisions limit what evidence the special master may consider in deciding whether a prima facie case has been established. *Doe 11 v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1358 (Fed. Cir. 2010) (citing *de Bazan*, 539 F.3d at 1353); *see also Walther v. Sec'y of Health & Human Servs.*, 85 F.3d 1146, 1151 (Fed. Cir. 2007). As a result, the government may also present and the special master may consider evidence of alternative causes on the issue of the adequacy of the petitioner's evidence regarding the petitioner's case-in-chief. *Doe 11*, 601 F.3d at 1358 (quoting *de Bazan*, 539 F.3d at 1354).

In this regard, there are two particular points that the decisions make clear. First, a special master may not require the petitioner to shoulder the burden of eliminating all possible alternative causes in order to establish a *prima facie* case. *Walther*, 485 F.3d at 1151-52; *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379-80 (Fed. Cir. 2012). Second, a special master may find that a factor other than a vaccine caused the injury in question only if that finding is supported by a preponderance of the evidence. *Stone*, 676 F.3d at 1379-80 (citing *Doe 11*, 601 F.3d at 1356–57); *see Walther*, 485 F.3d at 1151-52 (the petitioner does not bear the

burden of eliminating alternative independent potential causes, and the respondent has the burden of proving an alternative cause as the sole, unrelated factor that caused the injury by a preponderance of evidence).

It is established that a special master is entitled to, and should, consider the record as a whole in determining causation. 42 U.S.C. § 300aa-13(a)(1)(A). In considering the record, the Vaccine Act does not contemplate full blown tort litigation. *Knudsen,* 35 F.3d at 548. A petitioner may use circumstantial evidence to prove the case, and "close calls" regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280. Indeed, "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen,* 418 F.3d at 1280); *Capizzano*, 440 F.3d at 1324.

DISCUSSION

Having considered the record as a whole and discussed below, the special master concludes that Petitioners have satisfied their burden of establishing by preponderant evidence that they are entitled to compensation.

A. Petitioners Have Presented a Plausible Medical Theory, Molecular Mimicry, Along With Supporting Literature That the Vaccine Can Cause A.R.'s Injuries, Thereby Satisfying *Althen* Prong 1.

Petitioners have satisfied *Althen's* Prong 1 by presenting a plausible medical theory. In support of Prong 1, Petitioners' expert, Dr. Houff, described the process of molecular mimicry as a mechanism whereby the vaccine could cause an autoimmune response that could result in TM, what he had concluded A.R. experienced. Tr. at 140-141. This was also discussed in the article submitted filed as P's Ex. 32, Agnon-Levin, N., *Transverse Myelitis and Vaccines: A multi-analysis,* at 1201 (Ex. 32 at 113). Petitioners also submitted a number of other articles from various medical journals. *See e.g.*, P's Exs. 10.1 and 27. The medical literature submitted provided further support that it has been recognized that Tdap could cause TM. In particular, P's Exs., 10.1 and 27 discuss vaccines as causes of autoimmune responses, to include TM; *see also* P's Ex. 26. Those articles are evidence supportive of Petitioners' theory.

Respondent's expert, Dr. Sladky, did not deny that vaccines might cause autoimmune responses such as TM. In commenting on Petitioners' theory, without providing any particular reasoning, Dr. Sladky merely said, in a conclusory fashion, that he was not sure there was sufficient evidence on which to base Petitioners' conclusion regarding a theory. Tr. at 287.

Respondent's expert did admit that Petitioners had certainly submitted literature in support of their theory. Tr. at 287-290. Dr. Sladky expressed that the articles were not that persuasive because they showed the rarity of TM post-vaccine. Tr. at 288, 290. Nonetheless, Dr. Sladky admitted that there were case reports that supported the theory of TM as a complication of vaccinations, including Tdap. Tr. at 586.

For purposes of the Vaccine Program, Petitioners are not required to establish that there is epidemiological evidence to support their theory. *Andreu*, 569 F.3d at 1378. Rather, the

Vaccine Program acknowledges the rarity of vaccine-caused injuries, and, nonetheless, recognizes that compensation for such injuries is appropriate. *See Althen*, 418 F.3d at 1280 (the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body); s*ee also Knudsen*, 35 F.3d at 549 (explaining that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program").

Considering the evidence with these standards in mind, Petitioners have presented sufficient evidence to demonstrate a plausible medical theory by which the vaccine could have caused the condition with which Petitioners claim A.R. suffers, TM. Petitioners have satisfied *Althen's* Prong 1.

B. Petitioners Have Presented Preponderant Evidence That There Is a Logical Sequence of Cause and Effect Between the Vaccine and A.R.'s Injuries By Showing That A.R.'s Injuries Were Caused by An Autoimmune Response and Not an Embolism and that the Vaccine Was a Substantial Factor in Causing the Injury.

Petitioners claimed that A.R. suffered from transverse myelitis, an inflammatory demylinating condition in the central nervous system that was caused by an autoimmune response. Respondent, on the other hand, while not claiming to present an alternative cause or factor unrelated as a defense, nonetheless, argued that there was evidence that A.R.'s injury was more likely caused by an embolism obstructing blood from flowing down the spine. As such, according to Respondent, Petitioners had not satisfied their burden as to Prong 2.

The record demonstrates that there was evidence that A.R.'s clinical picture along with the diagnostic tests support that A.R.'s injuries were caused by an inflammation of the central nervous system that was caused by an autoimmune response. The record also demonstrates that there is preponderant evidence that the vaccine caused that injury.

1. Petitioners Have Shown By Preponderant Evidence That A.R. Experienced An Autoimmune Response.

Petitioners have presented sufficient evidence that A.R.'s symptoms were caused by an autoimmune response. First, Dr. Krousgrill, onr of A.R.'s treating physician, concluded that A.R. had TM, a condition caused by an autoimmune response.

In reaching her conclusion, Dr. Krousgrill relied on her examination of A.R., her review of medical records and her medical knowledge. One factor that Dr. Krousgrill considered was the progression of A.R.'s symptoms. Dr. Krousgrill noted that A.R.'s symptoms began with A.R. experiencing tingling in her legs shortly after receipt of the vaccination. Tr. at 10-12. The tingling in her legs was different than that she had experienced in the past. And, A.R. had also explained that for several hours before she went to the bathroom on August 5, 2006, A.R. had experienced tingling. Tr. at 10-11. This indicated that the onset was not the abrupt onset that occurred over a matter of minutes, a conclusion upon which Respondent's experts had relied in formulating their opinions. Instead, it was consistent with an autoimmune response, TM. Tr. at 10-11. Dr. Krousgrill also looked at the temporal relation and the MRI findings that indicated a focal inflammatory process in the central portion of the cord that involved the entire cord. Tr. at

12. In addition, although the CSF proteins were steadily high between the first and second lumbar punctures, the fact is that A.R. did not have many white blood counts. Tr. at 13. Finally, the appearance of oligoclonal bands in the central nervous system indicated an active infection or inflammation. Tr. at 13. The location of the lesion and broad extent of it shown on the MRI findings indicated that it was more likely this was a transverse process. Tr. at 12-13.

Dr. Houff testified that he concluded that A.R. suffered an autoimmune response. Tr. at 178. He based his conclusion on A.R.'s picture as a whole, *i.e.*, the clinical picture, the exam, the radiology, her spinal fluid and all the studies. Tr. at 178. In particular, the signal on the MRI findings from that indicated a widespread effect, from T-2 through T-7, the evidence of oligoclonal banding after the second tap, the elevated complement, her high level of C-1 inhibitor, and the emergency room finding some sensation above the knee but no sensation below the knees and a mild sensation above the knees to T-12 and her poor rectal tone and incontinence all indicated that A.R. experienced a progressive, autoimmune response. *Id.*

Additionally, Dr. Houff explained that A.R. met four of the criteria for TM as established by the Transverse Myelitis Working Group. R's Ex. E.[11] The four "inflammation" criteria that were present included abnormal godlinlim enhancement of the spinal cord, "a CSF pleocytosis," and "elevated CSF IgG index." Id. at 4. Those inflammatory markers within the spinal cord are critical factors to distinguish TM, a type of inflammatory myelopathy, from other non-inflammatory myelopathy, like "ischemia, radiation, epidural lipomatosis or fibrocartilagenous embolism." R's Ex. 3.

Petitioners' evidence shows that the presence of the majority of the criteria as well as the results of the independent evaluations support Petitioner's request. There is ample evidence to support Petitioners'

2. Respondent's Argument That The Cause of A.R.'s Injuries is Likely an Embolism, Infarction or FCE Versus TM Is Unreliable And Unsupported by the Facts.

Respondent's claims that there is evidence that A.R.'s injuries are more likely caused by an embolism is unsupported by the objective clinical and diagnostic evidence, and her expert's conclusions are unreliable. an this is Whereas both of Petitioners' expert neurologists, Dr. Krousgill and Dr. Houff presented logically, reliable testimony, Respondent's expert, Dr. Sladky's testimony did not present the same level of reliability.

First, Dr. Sladky admitted that the theory that this is an infarction cannot necessarily be shown. For instance, he admitted there was no evidence as to how an infarct might have happened because there is no evidence of any trauma. Tr. at 558-60. In part his conclusion is simply based on the fact that he "doesn't think that TM would behave in the fashion it did. Tr. at 556-558. And, he admitted that there was no evidence of severe back pain, something indicative of FCE. Tr. at 564-566.

[11] Transverse Myeltitis Consortium Working Group, *Proposed Diagnostic Criteria and Nosology of Acute Transverse Myelitis*, NEUROLOGY 59: 499-505 (2002). R's Ex. E.

And, the objective evidence indicated that A.R.'s conditions are unlikely due to an embolism. As Dr. Brown explained, based on the view of the MRI, this was not an infarction because there is not a focal lesion that one would expect to see in an infarction. Tr. at 323. Rather, the lesion is quite widespread, consistent with an autoimmune response. *Id.* And, the injury about which Respondent theorizes is also inconsistent with the anatomy of the blood supply to the spinal cord. Tr. at 324-25. For this theory to actually occur this disk material would have had to enter one of the lumbar arterials and somehow communicated with a vessel coming off the aorta, but that's not the way the arterial anatomy works. Tr. at 324. One has a small artery at each lumbar vertebral level supplying a small amount of the blood supply to the cauda equine, and there's not even a spinal cord at that level, but just nerve roots. *Id.* One can somehow have an embolism in one artery and have it somehow get to another part of the spinal cord. *Id.* That's not the way the arterial anatomy is constructed. *Id.*

Dr. Krousgrill testified that it was significant that the entire cord was affected and that inidicated this was TM versus an embolism. Tr. at 19-20. The two primary avenues for circulation to the cord are the anterior spinal artery. *Id.* It would be unusual to have an ischemia in all 3 vessels simultaneously all at the same level. *Id.* Unlike A.R.'s situation, when a spinal artery is involved it is typically an anterior or lateral cord syndrome with mild or mixed sensory results. *Id.* The clinical progression is not consistent with an infarction or embolism.

Additionally, Dr. Brown also reiterated that which Petitioners' other experts, Dr. Krousgrill and Dr. Houff, had already stated in connection with their conclusions of the lumbar punctures or spinal taps performed on August 6 as compared to those performed on August 10. Tr. at 314. It was significant that in the first tap there was not evidence of oligoclonal banding whereas in the section one there was because an inflammatory response in the spinal cord does not look full blown immediately. *Id.* It takes some time. *Id.* This objective, diagnostic evidence shows that there is a lack of support for Respondent's claimed cause and support for Petitioners' claim that A.R. experienced an autoimmune response.

Second, Respondent's expert, Dr. Sladky, acknowledged that there was a basis for a conclusion that A.R. had an autoimmune response. He admitted that some of the accepted criteria for TM were definitely present. Tr. at 555-56. He also admitted that there is respected literature that includes TM as a complication of vaccinations, including Tdap vaccinations. Tr. at 586. And he admitted that oligoclonal bands are indicative of an immune response. Tr. at 268-69.

In fact Dr. Sladky's explanation for the oligoclonal bands being in the serum and spinal fluid is not logical in light of the facts. He testified that there the presence of oligoclonal banding in serum and the spinal fluid even if it was infarction could be explained because IgG was produced originally in the serum as a result of immunization and was leaked into the spinal fluid through broken blood barrier resulting from infarction. Tr. at 541-43. But, Dr. Vezina disagreed that the banding would appear just in the course after a vaccine, saying it ws clearly an abnormal response. Tr. at 516.

Finally, a last factor in considering the reliability of his testimony that the special master must consider is the information that was revealed relative to Dr. Sladky's status at the time of his work on this case and testimony. In May 2013, it was revealed that Dr. Sladky's medical license had agreed not to practice medicine from August 2008 to March 2009 and then had agreed to a suspension of his license that lasted from June 2009 to March 2010. At that time his license was restored on a probationary basis, the probation finally terminating on July 2011. At the time he submitted his expert reports in this case, he was on probation. R's Exs. A and C. And, in discussing his qualifications at the hearing, no mention was made of these circumstances and such information was glossed over. Tr. at 248. In fact, in his testimony, Dr. Sladky said he was the Chief of Pediatric Dept at Emory University until 2009. *Id.* But, given he was not practicing medicine after August 2008, it is questionable whether that could be the case. Certainly, this leads the special master to pause when weighting the experts' opinions. For all the foregoing reasons, the special master does not find Dr. Sladky's testimony as reliable and persuasive as the testimony of Dr. Houff and Dr. Krousgill.

Dr. Vezina, Respondent's neuroradiologist, admitted in his testimony that although he thought TM was less likely, based on the MRI findings, A.R.'s injuries could be either spinal cord infarction or TM. Tr. at 414. He also testified that with regard to an infarction there would have to be some sort of trauma. Tr. at 470. He deferred to the neurologist on this but admitted that he needed more information before he could state that such trauma had occurred. Tr. at 470-471. He also acknowledged that A.R. had four of the recognized diagnostic criteria for TM, *i.e.,* (1) development of sensory, motor, or autonomic dysfunction attributable to the spinal cord; (2) bilateral signs and/or symptoms; (3) clearly defined sensory level (*assumes* we have this but doesn't have the medical records); (4) inflammation within the spinal cord demonstrated by CSF, or elevated IgG indexed. Tr. at 470-471. Dr. Vezina also testified that he had no direct evidence to prove that that Amber suffered an infarct from FCE. Tr. at 468. Finally, Dr. Vezina admitted that this was a close call and "it's not a clear vascular thing" because it's a focal lesion and on the whole cord. Tr. at 461.

In many ways, Dr. Vezina's testimony was consistent with Dr. Brown's testimony as well as Petitioners' other experts. He acknowledged that there was clearly clinical and diagnostic evidence that A.R. suffered from TM. As he stated this is a close call. In the Vaccine Program, Petitioners are accorded the benefit of close calls.

3. There Is Preponderant Evidence Showing the Vaccine to be a Substantial Factor In Causing the Autoimmune Response.

There is also preponderant evidence that the Tdap vaccine was a substantial factor in causing A.R.'s TM. Dr. Krousgrill, the treating physician, concluded that having looked at a number of potential etiologies, the vaccine was significant. Admittedly, she could not make this a definitive diagnosis based upon a standard of reasonable degree of medical certainty, but she certainly believed there was a relationship between the vaccine and A.R.'s TM. Tr. at 15. *Capizzano,* 440 F.3d at 1326 (treating physician's opinions should be considered).

Dr. Houff also explained that in this case he felt there was enough data to conclude within a reasonable degree of medical probability that the vaccine caused A.R.'s injuries. Tr. at

211. In so doing, he explained that it's very hard to conclude that vaccines cause injuries. Tr. at 210. He acknowledged the importance of vaccines. Tr. at 211. At the same time, based on his assessment of the clinical picture in this case, including (1) the progression of her illness, (2) the temporal association, (3) the lack of indication of another infection, the data was enough to conclude that the vaccine caused A.R. an aberrant immune response that attacked her nervous system, her spinal cord. Tr. at 211.

And, Dr. Brown also discussed how she had concluded that the vaccine caused A.R.'s injuries. She relied on the classic appearance of TM on the imaging study, the time frame and A.R.'s history up to that point. Tr. at 321-323.

Respondent's expert, Dr. Sladky did not definitively rule out the vaccine as a cause. Instead, in his expert report he simply stated he did not think Dr. Houff provided a compelling argument to support this position. R's Ex. A.

Weighing the testimony as presented, the special master finds that Petitioners' experts were more persuasive. They explained logically and methodically their reasoning for concluding the vaccine was a substantial factor. At the same time, they did not overstate their positions, instead acknowledging that it would be difficult, if not impossible, to prove the vaccine was the cause as a matter of medical certainty. On the other hand, Respondent's expert primarily presented a conclusory statement that he did not believe Petitioners had satisfied their burden.

In addition to that, the special master must also look at the cumulative evidence on all three prongs in that evidence that satisfies Prongs 1 and 3, can overlap and be used to satisfy Prong 2. *Capizzano,* 440 F.3d at 1326. Here, there is sufficient evidence to satisfy Prong 1. There is no question that Prong 3 has been satisfied. The treating physician, Dr. Krousgrill, having considered the clinical picture of A.R. at or near the time of the onset of symptoms looked for other potential causes and considered them but found none. Tr. at 8-9. Similarly, with regard to temporal relationship, there is not much question that it is satisfied. *See infra* VI.C. That evidence also overlaps and supports the evidence in the record relating to Prong 2.

In sum, Petitioners have presented sufficient proof to demonstrate satisfy their burden as to Prong 2. In particular, the MRI at the time of the onset of A.R.'s condition indicated a lesion with the entire spinal cord being involved, which is consistent with inflammation versus embolism. Additionally, the presence of oligoclonal banding, which was not present initially, and the fact that the CSF protein levels increased, are indicators that the cause was an immune mediated process, which would eliminate FCE as a potential cause. The fact that A.R. reported having heaviness in her legs for some time and even up to hours before her trip to the bathroom when she was unable to move and still had some feeling for a period afterwards indicates that this was not an abrupt onset as Respondent contends and upon which her expert bases his conclusions. And Petitioners have also presented preponderant evidence that the Tdap vaccine A.R. received was a substantial factor in causing that autoimmune response. Petitioners' experts carefully examined the record for other possible explanations, researched the medical literature.

In weighing the Petitioners' experts versus Respondent's experts, the special master concludes that Petitioners' experts' opinions are more reliable. In particular, A.R.'s treating

physician, Dr. Krousgrill, testified for Petitioners that she had concluded A.R. had TM. Dr. Houff gave a reasoned explanation that A.R. had TM and that the vaccine caused it. On the other hand, Dr. Sladky, Respondent's expert, admitted that embolisms were more rare than TM. Respondent's claims that the evidence of inflammation was unlikely does not seem consistent with the appearance of oligoclonal bands. Dr. Vezina said that the appearance of banding would not occur merely because someone had a vaccine. Tr. at 516. Rather, it was clearly an abnormal response.

Considering the supporting literature, the strong evidence of the temporal relation, the evidence of an autoimmune response and lack of any other possible etiology, there is sufficient evidence to show a logical sequence of cause and effect. Petitioners have satisfied *Althen's* Prong 2.

C. There is No Dispute as to *Althen* Prong 3.

Finally, that there is a medically-appropriate temporal relationship is not disputed. The parties agreed that the time frame between the receipt of the vaccine on July 6, 2006 and the onset of the injuries on August 5, 2006, is medially appropriate. Joint Prehearing Submission at 1.

CONCLUSION

Upon review of the evidence and an assessment of the reliability of the opinions of the various expert witnesses, the special master concludes that Petitioners have established by preponderant evidence that they are entitled to compensation. The matter shall now proceed to consideration of damages.

IT IS SO ORDERED.

__/s/ _____
Daria J. Zane
Special Master